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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/703,798	11/02/2000	Amanda Johanne Kiliaan	BO 44102 ACW	2164

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EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/703,798	KILIAAN ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-63,65-73 and 76-79* is/are pending in the application.

4a) Of the above claim(s) *73,78 and 79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-63, 65-72, 76, and 77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The applicant is apprised that the examiner in this case has changed.

The examiner notes the amendments to claims 56 and 66; the cancellation of claim 64; and the addition of claims 76-79. Claims 78 and 79 are withdrawn from consideration since they depend from claim 73, which was withdrawn by Examiner Davis on the prior action. Examination will continue at this time on claims 56-63, 65-72, 76, and 77 ONLY.

The examiner also notes the submission of a declaration under 37 C.F.R. § 1.132 authored by Dr. Ladislaus Broerson.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Prior art references can be found in a prior Office action, unless otherwise noted.

Claim Rejections - 35 USC § 112

Claims 56-63, 65-72, 76, and 77 are/remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record and further below. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

On the first Office action, Examiner Davis pointed out that claims to "prevention" of a condition require some substantive showing that the person of ordinary skill in the art would have a reasonable expectation of prevention. Examiner Davis also noted the

absence of working examples in which the claimed composition prevented any given condition.

Applicant has amended claim 56 such that it is drawn in part to treating a mammal at risk of developing dementia syndromes, cognitive degeneration, or hearing loss. The claim in its current form still reads on preventing these conditions. All individuals are at risk of developing these dementia syndromes, cognitive degeneration, or hearing loss. The issue of a so-called "prevention" claim has not been rectified by the amendment. Because claims 57-63, 65-72, 76, and 77 depend from nonenabled claim 56 and do not themselves enable the claims, they must also be rejected under 35 U.S.C., first paragraph.

Claims 56-63, 65-72, 76, and 77 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record and further below.

Claim 56 is confusing in that it requires a specific amount of DHA, but DHA is not required to be comprised in the composition (it is one of two options). It is not clear whether fraction (a) must comprise DHA. Clarification is required. Because claims 57-63, 65-72, 76, and 77 depend from indefinite claim 56 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C., second paragraph.

Claim 76 is are confusing, because it is not clear what combinations are encompassed and excluded by the claim. The claim, when considered in simplified

form, is drawn to a composition "comprising at least A, and at least B, and/or at least C", which is confusing. Clarification is required.

Claim 76 is further confusing in light of parent claim 56. Claim 56 requires that fraction (c) requires only one factor, while the language of claim 76 implies that a minimum of two are required. Clarification is required.

Claim Rejections - 35 USC § 103

Claims 56, 59 - 62, 65, 69 - 70, 72, 76, and 77 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Della Valle and Fugh-Berman for reasons of record and further below.

Applicant claims a composition suitable for treating a mammal having or at risk of developing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fatty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Fraction (a) further comprises at least one of linoleic acid, alpha-linloenic acid, and optionally an omega 6 fatty acids selected from DHGLA and AA; wherein the ratio or EPA+DHA+DHGLA+AA to the total amount of linoleic and alpha-linoleic acid is above 0.4 :1. The composition further comprises (d) citrates or citric acid; or (h) ginkgo biloba extract. Fraction (c) further comprises one of SAMe, choline, betaine or copper; the composition is a nutritional supplement. Specifically, the composition comprises at least 0.2 g phospholipids; 0.1 g

phosphatidylserine; or at least 120 mg long chain fatty acids, 200 mg phospholipids, 200 micrograms folic acid, and 500 mg citrate.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 - 75% phosphatidylserine and 25 - 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing

dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 56-58, 76, and 77 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Della Valle, Fugh-Berman and Taiyo Fishery Co. for reasons of record and further below.

Applicant claims a composition suitable for treating a mammal having or at risk of developing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fatty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Fraction (b) comprising PC, PE and PS; and the weight ration of PC and PE to PS is from 0.5 - 20:1

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 - 75% phosphatidylserine and 25 - 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Taiyo Fishery Co teaches compositions of phosphatidylcholine and phosphatidylethanolamine for treating Alzheimer's disease (abstract).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above. since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claim 63 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Della Valle, Fugh-Berman and Yu for reasons of record and further below.

Applicant claims a composition suitable for treating a mammal having or at risk of developing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fatty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. The composition further comprises huperzine A.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 - 75% phosphatidylserine and 25 - 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Yu teaches compounds for treating dementia (abstract) wherein huperzine A is a representative compound (col.4 line 24-25).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claim 65 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Smith for reasons of record and further below.

Applicant claims a composition suitable for treating a mammal having or at risk of developing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fatty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Fraction (c) further one of SAMe, choline, betaine or copper.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 - 75% phosphatidylserine and 25 - 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Smith teaches compositions for treating Alzheimer's disease, comprising folic acid, vitamin B12 (abstract), betaine, and/or vitamin B6 (col.2 line 43-52).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known

benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 65 and 66 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Hutterer for reasons of record and further below.

Applicant claims a composition suitable for treating a mammal having or at risk of developing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fatty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid,

vitamin B12, B6, magnesium or zinc. Fraction (c) further comprises one of SAME, choline, betaine, or copper; or zinc and copper at a specified ratio.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 - 75% phosphatidylserine and 25 - 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Hutterer teaches compositions comprising choline, zinc and copper (abstract) in specific amounts and ratios (col.4 line 13-23) for treating Alzheimer's disease (abstract).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have

been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claim 71 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Della Valle, Fugh-Berman, Smith, Hutterer and Glick for reasons of record and further below.

Applicant claims a composition suitable for treating a mammal having or at risk of developing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fatty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Specifically the composition comprises at least 20 mg EPA, 50 mg DHA, 50 mg AA, 200 mg phospholipids, 200 micrograms folic acid, 100 mg magnesium, 5 mg zinc, 2 mg vitamin B6, 2 micrograms vitamin B12 and 1g citrate.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic

acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 - 75% phosphatidylserine and 25 - 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Smith teaches compositions for treating Alzheimer's disease, comprising folic acid, vitamin B12 (abstract), betaine, and/or vitamin B6 (col.2 line 43-52).

Hutterer teaches compositions comprising choline, zinc and copper (abstract) in specific amounts and ratios (col.4 line 13-23) for treating Alzheimer's disease (abstract).

Glick teaches administering dietary supplements of magnesium for preventing and controlling dementia and memory loss (abstract, col.3).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have

been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Della Valle, Fugh-Berman and Rabien for reasons of record and further below.

Applicant claims a composition suitable for treating a mammal having or at risk of developing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fatty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. The composition further comprises (f) one or more selected from carnitine, vitamin B1, B5 and coenzyme Q10; or (g) one or more antioxidants selected from vitamin C, E, lipoic acid, selenium salt and carotenoids.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic

acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 - 75% phosphatidylserine and 25 - 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Rabien teaches compositions comprising alpha lipoic, panthothenic acid (vitamin B5) and vitamin E for treating Alzheimer's disease (abstract).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old

ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicants have argued that the declaration under 37 C.F.R. § 1.132 by Laus Broersen provides evidence of unexpected results, more specifically a showing that the coadministration of fatty acids and phospholipids "compensates for the loss of acetylcholine in dementia and support normal cognitive functioning in dementia" (Remarks, page 11). Applicants also assert that the declaration under 37 C.F.R. § 1.132 by Martijn de Wilde provides evidence that said coadministration causes "unexpected and improved blood vessel health and improved spatial memory" (Remarks, page 11). Applicants argue that the Office has not established that the nature of the invention is not derived from the combination of ingredients, recited amounts, and recited ratios set forth in the claims. Applicants also argue that the cited prior art teaches away from the claimed amounts and ratios (Remarks, page 14). These arguments have been fully considered, but they are not persuasive.

Regarding the de Wilde declaration, it is noted that the claims are not commensurate in scope with the composition (*i.e.*, "supplement 2") of the declaration, which exhibits the activities presented and argued. The instant claims do not recite each and every element of the composition demonstrated to have the unexpected advantage of improved capillary density, spatial memory qualities and MM performance.

Regarding the Broersen declaration, it is noted that the claims are not commensurate in scope with the experimental results presented in the declaration. The declaration provides insufficient quantitative information regarding the composition administered to the cells in order to determine whether the composition of the declaration is identical to one of the **claimed** embodiments. The composition of the declaration is merely described as comprising fatty acids and phospholipids, but no chemical names are provided. In addition, the declaration is unconvincing as it pertains to dementia and cognition, since the experiments therein are *in vitro* experiments conducted on mouse pancreas cells that express the muscarinic GPCR.

Because the specification and declarations fail to provide evidence of unexpected results for the composition **as claimed**, the amounts and ratios recited are a matter of routine optimization for the skilled artisan. it would have been obvious to one of ordinary skill in the art to optimize the amounts of known active ingredients for the same purpose, as a matter of routine practice. At the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients and to optimize the amounts, with a reasonable expectation for successfully obtaining a composition effective for treating dementia syndromes.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 9:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

leb

LEON B. LANKFORD, JR.
PRIMARY EXAMINER